

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
74-793

MICROBIOLOGY REVIEW

DIVISION OF CHEMISTRY I
OFFICE OF GENERIC DRUGS

-Microbiologist's Review #2

July 1, 1997

A. 1. ANDA: **74-793 - Minor Amendment**

APPLICANT: MOVA Pharmaceutical Corporation
Attention: Angel L. Rodriguez-Arce
P.O. Box 8639
Caguas, Puerto Rico 00626

2. PRODUCT NAMES: **Lorazepam Injection, USP**

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

2 mg/mL & 4 mg/mL packaged for intramuscular (undiluted) or intravenous (diluted) injection as follows:

1 mL fill in a 2 cc vial
10 mL fill in a 10 cc vial

4. METHOD(S) OF STERILIZATION: ---

5. PRINCIPLE INDICATIONS: Preanesthetic medication, producing sedation, relief of anxiety and a decreased ability to recall events related to the day of surgery

6. PHARMACOLOGICAL CATEGORY: Anti-anxiety drug/pre-sedative

B. 1. DATE OF INITIAL SUBMISSION: **November 22, 1995**

2. DATE OF AMENDMENT:

June 9, 1997 (Received by OGD on 6/16/97)

- Subject of this Review

3. RELATED DOCUMENTS:

DMF

3. RELATED DOCUMENTS (continued):

4. ASSIGNED FOR REVIEW: June 24, 1997

C. REMARKS: The information provided in the amendment was sufficient to determine that the applicant is taking the necessary steps to ensure the sterility of the subject drug product (Lorazepam Injection, USP).

D. CONCLUSIONS: The submissions are therefore now recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes."

Kenneth H. Muhvich 7/1/97
Kenneth H. Muhvich, Ph.D.

See p. 6

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Information and are not

releasable.

Micro Rev. 2

7/1/97

DIVISION OF CHEMISTRY I
OFFICE OF GENERIC DRUGS

- Microbiologist's Review #1

March 5, 1996

A. 1. ANDA: **74-793**

APPLICANT: MOVA Pharmaceutical Corporation
Attention: Dale Robson
P.O. Box 8639
Caguas, Puerto Rico 00626

2. PRODUCT NAMES: **Lorazepam Injection, USP**

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

2 mg/mL & 4 mg/mL packaged for intramuscular (undiluted)
or intravenous (diluted) injection as follows:

1 mL fill in a 2 cc vial
10 mL fill in a 10 cc vial

4. METHOD(S) OF STERILIZATION:

5. PRINCIPLE INDICATIONS: Preanesthetic medication, producing
sedation, relief of anxiety and a decreased ability to
recall events related to the day of surgery

6. PHARMACOLOGICAL CATEGORY: Anti-anxiety drug/pre-sedative

B. 1. DATE OF INITIAL SUBMISSION:

November 22, 1995 (Received by OGD on 11/27/95)
- Subject of this Review

2. DATE OF AMENDMENT: N/A; no amendments containing sterility
assurance information were submitted by the time of this
review

3. RELATED DOCUMENTS:

3. RELATED DOCUMENTS (continued):

Inc. of
where
ative efficacy
type I glass vials

4. ASSIGNED FOR REVIEW: February 29, 1996

C. REMARKS: Most of the sterility assurance information was found in Section XI of the application. However, the information provided was insufficient to determine if the applicant is taking the necessary steps to ensure the sterility of the subject drug product (Lorazepam Injection, USP). For example, a microbial challenge seal integrity test was not performed for the container/closure systems proposed for the subject drug products.

D. CONCLUSIONS: The submissions are therefore not recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiologist's Draft Letter to the Applicant".

Kenneth H. Muhvich 3/5/96

Kenneth H. Muhvich, Ph.D.

15/96

RR/td 3/6/96

cc:

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Micro Rev. 1

3/5/96